Complete Summary

GUIDELINE TITLE

Dyslipidemia management in adults with diabetes.

BIBLIOGRAPHIC SOURCE(S)

Haffner SM. Dyslipidemia management in adults with diabetes. Diabetes Care 2004 Jan;27(Suppl 1):S68-71. [10 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Cardiovascular disease
- Diabetes mellitus
- Dyslipidemia

GUIDELINE CATEGORY

Management
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Dietitians
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for therapy of diabetic dyslipidemia in order to reduce the risk of cardiovascular disease in patients with diabetes mellitus

TARGET POPULATION

Adults, adolescents, and children with diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

1. Screening with lipid assessments
2. Lifestyle modification focusing on the reduction of saturated fat and cholesterol intake, weight loss, increased physical activity, and smoking cessation
3. Improved glycemic control
4. Modification of lipoproteins by medical nutritional therapy and physical activity
5. Modification of lipoproteins by glucose-lowering agents
6. Low-density lipoprotein cholesterol lowering therapy
7. High-density lipoprotein cholesterol raising therapy
8. Triglyceride-lowering therapy
9. Combined hyperlipidemia therapy
10. Other lipid-lowering pharmacologic agents

MAJOR OUTCOMES CONSIDERED

- Risk of cardiovascular disease
- Mortality rate associated with cardiovascular disease

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations have been assigned ratings of A, B, or C, depending on the quality of evidence (see table below). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are based on large, well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

American Diabetes Association's evidence grading system for clinical practice recommendations:

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

- Compelling non-experimental evidence, i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford*

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review: This position statement was peer-reviewed, modified, and approved by the American Diabetes Association's Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

Recommendations of Others: The following groups' recommendations for management of dyslipidemia were discussed: The American Heart Association and the National Cholesterol Education Program.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grading system for clinical practice recommendations (A through C, E) is defined at the end of the "Major Recommendations" field.

Screening

In adult patients, test for lipid disorders at least annually and more often if needed to achieve goals. In adults with low-risk lipid values (low-density lipoprotein [LDL] <100 mg/dL, high-density lipoprotein [HDL] >50 mg/dL, and triglycerides <150 mg/dL), repeat lipid assessments every 2 years. (E)

Treatment Recommendations and Goals

- Lifestyle modification focusing on the reduction of saturated fat and cholesterol intake, weight loss, increased physical activity, and smoking cessation has been shown to improve the lipid profile in patients with diabetes. (A)
- Patients who do not achieve lipid goals with lifestyle modifications require pharmacological therapy. (A)
- Lower LDL cholesterol to <100 mg/dL (2.6 mmol/L) as the primary goal of therapy for adults. (B)
- Lowering LDL cholesterol with a statin is associated with a reduction in cardiovascular events. (A)
- In people with diabetes over the age of 40 years with a total cholesterol $\geq$135 mg/dL, statin therapy to achieve an LDL reduction of approximately 30% regardless of baseline LDL levels may be appropriate. (A)
- In children and adolescents with diabetes, LDL cholesterol should be lowered to <100 mg/dL (2.60 mmol/L) using medical nutrition therapy (MNT) and medications, based on LDL level and other cardiovascular risk factors in addition to diabetes. (E)
- Lower triglycerides to <150 mg/dL (1.7 mmol/L), and raise HDL cholesterol to >40 mg/dL (1.15 mmol/L). In women, an HDL goal 10 mg/dL higher may be appropriate. (C)
- Lowering triglycerides and increasing HDL cholesterol with a fibrate is associated with a reduction in cardiovascular events in patients with clinical cardiovascular disease (CVD), low HDL, and near-normal levels of LDL. (A)
- Combination therapy using statins and fibrates or niacin may be necessary to achieve lipid targets, but has not been evaluated in outcomes studies for either event reduction or safety. (E)

Definitions:

American Diabetes Association's evidence grading system for clinical practice recommendations:

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence, i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford*

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Aggressive therapy of diabetic dyslipidemia will reduce the risk of cardiovascular disease in patients with diabetes.

POTENTIAL HARMS

- The combination of statins with nicotinic acid, fenofibrate, and especially with gemfibrozil has been associated with an increased risk of myositis although the risk of clinical myositis (as opposed to elevated creatinine phosphokinase levels) appears to be low. However, the risk of myositis may be increased with the combination of gemfibrozil and a statin or in patients with renal disease. Nicotinic acid should be used with caution in patients with diabetes.
- Gemfibrozil should not be initiated alone in diabetic patients who have undesirable levels of both triglyceride and low density lipoprotein (LDL) cholesterol.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- There is relatively little observational data on lipoproteins and cardiovascular disease (CVD), and there are no clinical trials relating lipoproteins to CVD.
- No completed clinical trials have examined the effect of implementing different lipid treatment goals, including the question of what low density lipoprotein (LDL) cholesterol goal should be used and whether the use of multi-drug therapy is more effective than monotherapy for patients with complex lipid abnormalities. Current trials are examining these questions.
- Evidence is only one component of decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances such as comorbid and coexisting diseases, age, education, disability, and above all, patient's values and preferences must also be considered and may lead to different treatment targets and strategies.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Haffner SM. Dyslipidemia management in adults with diabetes. Diabetes Care 2004 Jan;27(Suppl 1):S68-71. [10 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 Nov (revised 2004 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

The American Diabetes Association received an educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2004 Diabetes Care Supplement.

GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Author of Position Statement, Initial Draft: Steven M. Haffner, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: Haffner SM. Management of dyslipidemia in adults with diabetes. Diabetes Care 2003 Jan;26 Suppl 1:S83-6.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 1, 1998. The information was verified by the guideline developer on December 15, 1998. It was updated by ECRI on April 1, 2000, April 2, 2001, March 14, 2002, July 29, 2003, and May 26, 2004.

COPYRIGHT STATEMENT

Date Modified: 11/15/2004